§ 522.234

(3) Limitations. Do not administer to horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 70998, Nov. 25, 2005]

§ 522.234 Butamisole hydrochloride.

- (a) *Specifications*. The drug contains 11 milligrams of butamisole per milliliter in a solution consisting of 70 percent propylene glycol, 4 percent benzyl alcohol and distilled water.
- (b) *Sponsor*. See Nos. 000859 and 053501 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is administered by subcutaneous injection to dogs for the treatment of infections with whipworms (Trichuris vulpis), and the hookworm (Ancylostoma caninum).
- (2) The drug is administered subcutaneously at the rate of 0.1 milliliter per pound of body weight. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- [43 FR 15625, Apr. 14, 1978. Redesignated at 43 FR 60883, Dec. 29, 1978, and amended at 45 FR 29789, May 6, 1980; 51 FR 19329, May 29, 1986; 67 FR 63055, Oct. 10, 2002]

§522.246 Butorphanol.

- (a) Specifications. Each milliliter of solution contains butorphanol (as butorphanol tartrate) in the following amounts:
 - (1) 0.5 milligrams (mg);
 - (2) 2 mg; or
 - (3) 10 mg
- (b) Sponsors. See sponsors in §510.600(c) of this chapter as follows:
- (1) No. 000856 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section; for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section; and for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.
- (2) No. 000859 for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

- (3) Nos. 000061, 000859, and 061690 for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.
- (c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (d) Conditions of use—(1) Dogs—(i) Amount. Administer 0.025 mg per pound of body weight by subcutaneous injection at intervals of 6 to 12 hours, as required. If necessary, increase dose to a maximum of 0.05 mg per pound of body weight. Treatment should not normally be required for longer than 7 days.
- (ii) Indications for use. For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.
- (2) Cats—(i) Amount. Administer 0.2 mg per pound of body weight by subcutaneous injection. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days.
- (ii) *Indications for use*. For the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures.
- (3) Horses—(i) Amount. Administer 0.05 mg per pound of body weight by intravenous injection. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours.
- (ii) *Indications for use*. For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.
- (iii) *Limitations*. Do not use in horses intended for human consumption.
- $[72\ FR\ 27957,\ May\ 18,\ 2007,\ as\ amended\ at\ 73\ FR\ 31358,\ June\ 2,\ 2008;\ 74\ FR\ 61516,\ Nov.\ 25,\ 2009;\ 75\ FR\ 22524,\ Apr.\ 29,\ 2010;\ 77\ FR\ 60302,\ Oct.\ 3,\ 2012;\ 78\ FR\ 17597,\ Mar.\ 22,\ 2013]$

§ 522.275 N-Butylscopolammonium bromide.

- (a) Specifications. Each milliliter of solution contains 20 milligrams (mg) N-butylscopolammonium bromide.
- (b) Sponsor. See No. 000010 in §510.600(c) of this chapter.
- (c) Conditions of use in horses—(1) Amount. 0.3 mg per kilogram of body weight (0.14 mg per pound) slowly intravenously.

Food and Drug Administration, HHS

- (2) *Indications for use*. For the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 35512, June 25, 2004]

§ 522.300 Carfentanil citrate injection.

- (a) *Specifications*. Each milliliter of sterile aqueous solution contains 3 milligrams of carfentanil citrate.
- (b) *Sponsor*. See No. 053923 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. 5 to 20 micrograms per kilogram (.005 to .020 milligram per kilogram) of body weight.
- (2) Indications for use. For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).
- (3) Limitations. Inject into large muscle of neck, shoulder, back, or hindquarter. Avoid intrathoracic, intra-abdominal, or subcutaneous injection. To reverse effect, use 7 milligrams of diprenorphine for each milligram of intracarefentanil citrate, given venously or one-half intravenously and one-half intramuscularly orsubcutaneously. Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Do not use in animals that display clinical signs of severe cardiovascular or respiratory disease. Available data are inadequate to recommend use in pregnant animals. Avoid use during breeding season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

[53 FR 40057, Oct. 13, 1988. Redesignated at 73 FR 29685, May 22, 2008]

§522.304 Carprofen.

- (a) Specifications. Each milliliter of solution contains 50 milligrams (mg) carprofen.
- (b) Sponsor. See No. 000069 in §510.600(c) of this chapter.
 - (c) [Reserved]

- (d) Conditions of use in dogs—(1) Amount. 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection. For the control of postoperative pain, administer approximately 2 hours before the procedure.
- (2) Conditions of use. For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26205, May 15, 2003, as amended at 68 FR 34796, June 11, 2003; 68 FR 49351, Aug. 18, 2003. Redesignated at 73 FR 29685, May 22, 2008]

§522.311 Cefovecin.

- (a) Specifications. Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.
- (b) Sponsor. See No. 000069 in §510.600(c) of this chapter.
- (c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (d) Conditions of use—(1) Dogs—(i) Amount. Administer 3.6 mg/pound (lb) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.
- (ii) Indications for use. For the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of Staphylococcus intermedius and Streptococcus canis (Group G).
- (2) Cats—(i) Amount. Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.
- (ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

[73 FR 29685, May 22, 2008]